MAXIMUM STRENGTH BURN RELIEF ALOE GEL SCHERER LABS- lidocaine hydrochloride 4.00% gel
Product Quest Mfg.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredients	Purpose
Lidocaine Hydrochloride - 4.00%	Topical analgesic

Uses

For the temporary relief of pain and itching due to • sunburn • minor burns • insect bites • minor cuts • scrapes • minor skin irritation

Warnings
For external use only.
When using this product • avoid contact with eyes. Rinse with water if contact occurs.
Stop use and ask doctor if • if symptoms persist for more than 7 days.
Do not use in large quantities, particularly over raw surfaces or blistered areas.

Keep out of the reach of children

Directions

• Adults and children 2 years and older: apply to affected area not more than 3-4 times a day. • Children under 2 years of age: consult a physician.

Inactive ingredients

Aloe Barbadensis Leaf Extract, Avena Sativa (Oat) Kernel Extract, Blue 1, Caprylyl Glycol, Chlorphenesin, Dimethyl Isosorbide, Glycerin, Hydroxyethylcellulose, Isopropyl Alcohol, Phenoxyethanol, Polysorbate 20, Propanediol, Tocopheryl Acetate, Water.

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lidocaine hydrochloride 4.00% gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64048-5002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Lidocaine Hydrochloride (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
OAT (UNII: Z6J799EAJK)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
Caprylyl Glycol (UNII: 00YIU5438U)	

Chlorphenesin (UNII: I670DAL4SZ)	
Dimethyl Isosorbide (UNII: SA6A6V432S)	
Glycerin (UNII: PDC6A3C0OX)	
Isopropyl Alcohol (UNII: ND2M416302)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
Propanediol (UNII: 5965N8W85T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64048-5002-4	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/08/2016	

Labeler - Product Quest Mfg. (927768135)

Registrant - Product Quest Mfg. (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg.		927768135	manufacture(64048-5002) , label(64048-5002)

Revised: 5/2018 Product Quest Mfg.